



# The Politics of Steroid Contraceptives: The FDA's Impact on Birth Control in the United States

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The Politics of Steroid Contraceptives:  
The FDA's Impact on Birth Control in the United States

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#### Abstract:

Steroid contraceptives were created during a period of societal support of pharmaceutical research and development and a climate of eugenics. The eugenics movement, which sought a solution to expanding poor and uneducated populations, overlapped with an emerging feminist goal of providing women with alternatives to lives based upon motherhood. Since the first introduction of steroid contraception in the form of the Pill, development of contraception and FDA involvement therein has followed the political tides, which, coupled with an increasingly litigious society, has chilled contraceptives research and development. Further dampening may also be attributed to the linkage between contraceptives and abortion in the law and in the public's perception. In order to reverse the trend of research withdrawal, action will be necessary on several fronts: tort reform by means of an FDA defense is necessary as well as required insurance coverage of steroid contraceptives and increased public funding.

## Contents

Introduction		4
I. De- vel- op- ment of steroid con- tra- cep- tives	6	
		a. Birth control to the masses
		b. The tech- nology of the Pill
	c. Steroid con- tra- cep- tion in the wake of the Pill	17
	d. Contra- ception devel- opment under the stricter FDA regime	

II. Political and Economic Barriers:	31	
	a. Costs of development	
	b. Abortion's impact on contraception	
III. Suggestions for removing the roadblocks to development	44	
Conclusion		47
References		

## Introduction

Theoretically, one of the greatest triumphs of mankind would be the elevation of procreation into a voluntary and deliberate act. – Sigmund Freud, 1898<sup>1</sup>

The creation of steroid contraception, first in the form known as “The Pill” and later in a variety of delivery systems, provided the “great triumph” envisioned by Freud a half century before. While many shared in Freud’s vision, the Pill was not a triumph in the minds of all members of society, and since its invention, steroid contraception has followed the waves of public perceptions of birth control, family planning, and sexuality. With roots in eugenics and feminism, the Pill has evolved into a political dividing point with links to abortion and to divergent moral values in the United States. As political power and public opinion has shifted, so too has the FDA’s treatment of the Pill and other forms of contraception, leaving contraceptives research and development uncertain and deteriorating. At the same time, an increasingly litigious society has driven the price of contraceptives to an often prohibitively high level while most healthcare provider organizations do not cover steroid contraception.

This paper examines the history of steroid contraception and the entities affecting contraceptives research and development, and offers suggestions on steps that might reverse the withdrawal from contraceptives research and development that occurred almost immediately after the Pill entered the market and has continued ever since. Part I traces the timeline of contraceptives development, from the birth of the Pill in the eugenics and feminist movements, through periods of changing FDA involvement in research and development and different political treatments of contraceptives. Part II examines the political and economic pressures on contraceptives research and development and how FDA policy is shaped in response to those pressures. Finally, Part III provides

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<sup>1</sup>Carl Djerassi, *This Man’s Pill: Reflections on the 50<sup>th</sup> Birthday of the Pill* 18 (2001).

a set of changes in FDA and legal policy that might help to reverse the withdrawal of major manufacturers from contraceptives research and development.

## I. The Development of Steroid Contraceptives

Steroid contraceptives, which comprise the menu of pharmaceutical, non-barrier contraceptives currently available, were created during a period of public awe with regard to technological breakthroughs in the field of applied biochemistry. The field had recently yielded chemotherapy, an effective treatment for cancer when none had been available before, and society was generally supportive of research and the new drugs such research yielded. Furthermore, legal perceptions of birth control were shifting due to a Supreme Court decision protecting the privacy of the marital bedroom.<sup>2</sup> At the same time, certain circles of society had become more interested in the public welfare, for both benevolent and selfish reasons, and chose to seek solutions to society's problems by combating poverty. Thus conditions were right for a drug, a chemical form of contraception, that could reduce population growth, a factor associated with poverty, and allow women more freedom from constant childbearing. This section first examines the history of the development first oral contraceptive, its early political reception, and its evolution into the menu of steroid-based birth control options available today. We begin with an examination of modern birth control's roots in the feminist and eugenics movements of the mid-twentieth century. Next, we review the story of the technological developments leading to the Pill, followed by the FDA's reaction to the political response to the Pill and the resulting period of heightened regulation of steroid contraception. Finally, this section concludes with an overview of the types of steroid contraception currently available or in development for distribution in the foreseeable future.

a. Birth Control to the masses, the development of the Pill as a result of the eugenics and feminist movements.

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<sup>2</sup>See *Griswold v. Mack*, 381 U.S. 479 (1965). (Stating that the marital relationship falls within a zone of privacy protected by the Constitution and that a law forbidding the use of contraceptives impacts that relationship.) See also *Eisenstadt v. Baird*, 405 U.S. 438 (1972). (Lifting a similar ban on contraception use by unmarried persons.)



Women should first free themselves from biological slavery, which could best be accomplished through birth control.<sup>3</sup>

I consider that the world and almost out civilization for the next century is going to depend on a simple, cheap, safe contraceptive to be used in poverty stricken slums, jungles, and among the most ignorant people.<sup>4</sup>

When Margaret Sanger issued those words in 1938 and 1950, respectively, she invoked the spirit of a feminist battle she led for decades and provided the context for what may be considered the most significant legacy of the American eugenics movement of the early twentieth century. That legacy, an oral contraceptive known worldwide simply as “The Pill,” forever altered the roles of women in society and cleared the way for what has been labeled the “Age of Biointervention.”<sup>5</sup> The political, moral, and scientific struggles to develop an oral contraceptive is one that set the stage for coming decades of dispute between medicine and morality, genetics and God.

Throughout the ages, women of almost every culture have attempted to avoid pregnancy. The strain of multiple childbirths (often upwards of ten) decimated the health and vitality of mothers and burdened family resources. Early, homemade or homeopathic attempts at contraception were directed towards either blocking pregnancy, or decreasing sex drive.<sup>6</sup> Centuries before Christ, women were using “magic”, potions, and pessaries to block conception.<sup>7</sup> The most common form of pregnancy prevention was *coitus interruptus*, which was highly ineffective at the time<sup>8</sup> and has remained so throughout the ages.<sup>9</sup> Natural oral contraceptives were also used, varying from basic teas to elaborate concoctions of root and animal extracts. Condoms appeared in the eighteenth century and were followed in the nineteenth century by the vaginal sponge.<sup>10</sup>

In the early twentieth century the most effective form of contraception was the diaphragm coupled with sper-

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<sup>5</sup>See *id.* at 7.

<sup>6</sup>See *id.* at 75.

<sup>7</sup>See *id.*

<sup>8</sup>See *id.*

<sup>9</sup>*Coitus interruptus* remains a common but unreliable method of contraception in the U.S. today. (See Tables 4 and 5, *infra*, for current usage and failure rates)

<sup>10</sup>See, Asbell, *supra* at 75.

micidal jelly. However, the contraceptive was not widely known and was often referred to as the “rich woman’s secret.”<sup>11</sup> Thus began Sanger’s search for a more widely available form of contraception.

As a nurse in New York City, Sanger came across numerous cases of mothers, who had often given birth to twelve or thirteen children, living in fear of another pregnancy. Sanger associated such mothers and their families with “poverty, toil, unemployment, drunkenness, cruelty, fighting, jails” while families that remained smaller were likely to enjoy better financial and social stature.<sup>12</sup> She later coupled this with the principles of eugenics that associated lower social classes with genetic inferiority. If one could provide birth control to the women of lesser means, one could relieve the burden of the poor and genetically inferior from society.<sup>13</sup>

Opinion on contraception throughout the rest of the eugenics movement was split. Since the majority of contraceptive users were affluent white Anglo-Saxon Protestants, many eugenicists were concerned that contraceptives would further the declining birthrate of offspring from what they considered the ideal gene pool. Charles Davenport, as the main leader of the faction against birth control, argued that contraceptives would only be used by those the eugenics movement wanted to encourage to procreate.<sup>14</sup> Others in the eugenics supported Sanger’s justifications for birth control: that if contraceptives could be given to the poor and uneducated, it would help to limit their reproduction and therefore the negative effects of the poor on society.<sup>15</sup>

Even before the Pill, however, distribution of contraceptives presented significant challenges. In a legal context, distribution was difficult since most states at the time prohibited even the distribution of information about contraception.<sup>16</sup> In 1948, eleven years after it became legal to ship contraceptives, only two percent of working class women were using diaphragms and among those who had a diaphragm fitted, half discontinued use within a year.<sup>17</sup> The “interruption” of inserting the diaphragm and the taboos of its application were too inconvenient

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<sup>11</sup>See *id.* at 77.

<sup>12</sup>See *id.* at 21.

<sup>13</sup>David M. Kennedy, *Birth Control in America* 113 (1970).

<sup>14</sup>Mark H. Haller, *Eugenics* 91 (1963)

<sup>15</sup>See Kennedy at 115.

<sup>16</sup>See Asbell at 80-81. The Comstock Law federally prevented both the personal distribution and distribution by mail of contraception information on obscenity grounds.

<sup>17</sup>See *id.* The issue of discontinued use has been a problem with many forms of contraception discussed *infra*.

and uncomfortable. By contrast, at the same time 41.7 percent of middle class women were using diaphragms.<sup>18</sup>

Contraceptives were missing their eugenic target.

No eugenic objectives could be realized if the lower classes could not gain access to contraception *en masse*, and with reliance on the diaphragm, this simply would not happen. What was needed, Sanger decided, was an oral contraceptive that could be taken “like aspirin.”<sup>19</sup> An oral contraceptive would not have as uncomfortable an application, nor could it be said to interfere with intercourse. Thus Sanger and associate Katherine McCormick provided financial and social support to Gregory Pincus, who was researching the use of recently developed steroid technology in the area of contraception.<sup>20</sup> *Enovid, the resulting oral contraceptive met the objectives of Sanger and McCormick, a source of birth control that did not interrupt sexual intercourse that provided reliable protection from pregnancy.*<sup>21</sup>

In the period between the Pill’s first availability in late 1959 and 1965, the number of women requesting contraception at Planned Parenthood rose by forty-seven percent, and by 1966, twenty-four percent of white American women were on the Pill.<sup>22</sup> From a feminist perspective, the Pill advanced opportunities for women by allowing them to contemplate a life outside the home and motherhood. A career was much more attainable when the anticipation of a pregnancy was not a constant consideration.<sup>23</sup>

But what of eugenics? Results were mixed. In 1964, President Johnson passed a measure providing birth control for the poor.<sup>24</sup> His administration established more than two thousand birth control clinics, and at

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<sup>18</sup>See *id.*

<sup>19</sup>See *id.* at 6.

<sup>20</sup>See *id.*

<sup>21</sup>See *id.* at 152. In clinical trials, Enovid exhibited a failure rate of approximately one percent. At the same time diaphragms had a 33.6 percent failure rate, suppositories 42.3 percent, spermicidal creams 36.1 percent, and condoms 28.3 percent.

<sup>22</sup>See *id.* at 176. Studies also showed that seventy percent of those who started on the Pill had not discontinued use two years later.

<sup>23</sup>A minority of feminist writers, however, argues that the Pill harmed women in the workplace by giving employers more influence over pregnancy decisions. Since pregnancy became a plannable event, some feminists would argue that a woman might be coerced into using contraception until it was convenient for her employer for her to have a child. See Djerassi, *This Man's Pill* at 78-80.

<sup>24</sup>See Asbell at 233-37.

these clinics the Pill was the most common form of birth control distributed. The Nixon Administration also supported family planning, and by 1973, approximately four million American women were using government-supplied contraception. The hope was that the distribution of contraceptives to the poor would stem their population growth and thus reduce government assistance costs.<sup>25</sup>

At the same time government-provided contraception was spreading, there was what could be considered a eugenic backlash. The National Association for the Advancement of Colored People (NAACP) discouraged African American women from using the pill.<sup>26</sup> Since African Americans comprised only ten percent of the population, the NAACP held that allowing contraception to limit the expansion of the black population was equivalent to racial suicide. Interestingly, this was the same argument that eugenicists had used to discourage affluent white women from using contraception decades before.

The Pill also had the negative effect on eugenics predicted by Davenport. Since women could control pregnancy, the eugenically ideal educated women were not becoming pregnant or at least were choosing to have fewer children.<sup>27</sup> Further studies showed that poor women of any race were more reluctant than affluent women to use birth control. This is not altogether surprising, since at poorer women at the time would have been much less likely to have had opportunity to work outside the home.<sup>28</sup> While birth control did reach some poor women, it was more often those women seeking social mobility, not those Sanger had intended to weed out eugenically.<sup>29</sup>

*Roe v. Wade* changed the course of federal funding for contraception as it became linked with the political

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<sup>25</sup> “[T]he rhetoric used to promote federal family planning in the 1960s and early 1970s was linked primarily to antipoverty measures. Within the context of the Great Society and the War on Poverty, this argument allowed the formation of a policy coalition around the belief that federal involvement in contraception would reduce welfare costs and dependency.” Donald T. Critchlow, *Intended Consequences* 229 (1999).

<sup>26</sup> See Asbell at 233-37. See also Critchlow at 142-147. (Discussing the disproportionate number of African American women receiving government contraception or sterilization as an indication of an intention to reduce or eliminate the African American population.)

<sup>27</sup> See KENNEDY at 125. *The opportunity to have a life outside the home and to have a higher quality of life, not plagued by the health problems associated with multiple pregnancies, outweighed the desire for prolific motherhood.*

<sup>28</sup> Id. As described at the time by Lee Rainwater, “Motherhood is much more completely [the poor woman’s] reason for being than it is for the middle class woman, who is taught the value of outside interests for establishing her validity as a person.”

<sup>29</sup> See Asbell at 272.

and social debate over abortion. When Ronald Reagan took office in 1980 (a race won largely by appealing to the conservative voter, a voter more likely to oppose abortion), his appointments to head the Department of Health and Human Services were consistently anti-abortion and anti-contraception.<sup>30</sup> Otis R. Bowen, appointed Secretary of HHS in 1985 specifically sought to limit access to abortion and contraception. His most damaging action was to cut federal funds from clinics that performed or counseled abortions a measure known as the Gag Rule. Since many of the clinics providing federally funded contraception also provided or at least counseled abortions, the Gag Rule effectively reduced the federal funding for contraception distribution. The Bush Administration continued the tightening of family planning dollars which *en toto* decreased by one percent in real dollars over the course of the two Republican administrations. Funding for contraceptives research was cut much more significantly, falling from \$38 million to \$7.5 million between 1974 and 1985.<sup>31</sup> Much of the reduction in public access to contraception was reversed during the Bill Clinton took office in 1992. Upon taking office Clinton immediately moved to overturn the Reagan-Bush antiabortion policy, including a lifting of the Gag Rule and the ban on the importation of RU 486, an abortifacient to be discussed *infra*.<sup>32</sup> Between 1992 and 1994, federal and state funding for contraception increased by eleven percent. As funding increased then decreased then increased again, much of the original eugenic rhetoric of abortion survived under the label of a war on poverty, without the troubled label of eugenics.<sup>33</sup> Today the principles of eugenics are seldom touted in policy decisions, but the fulfillment of the eugenics plan may be closer to completion than ever before. Although the principle behind the Pill was unrestrained accessibility to the masses, the Pill has become increasingly exclusive in its distribution. Many health insurance programs do not cover prescriptions for the Pill, and at average costs of twenty to forty dollars per month, the Pill is

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<sup>30</sup>See Critchlow at 213. See also, Carl Djerassi, *The Bitter Pill*, 245 *Science* 356, 357 (1989).

<sup>31</sup>See William M. Brown, *Déjà Vu All Over Again: The Exodus from Contraceptive Research and How to Reverse It*, 40 *Brandeis L.J.* 1, 2 (2001). (citing Elizabeth B. Connell, *The Crisis in Contraception*, 90 *Tech. Rev.* 46, 46 (1987).)

<sup>32</sup>See *id.* at 221.

<sup>33</sup>See *id.* at 231. (Quoting Kristin Luker, *Dubious Connections: The Politics of Teenage Pregnancy* 192 (1996). “[T]he rates of pregnancy and childbearing among teenagers are a serious problem, . . . early childbearing doesn’t make women poor; rather, poverty makes women bear children at an early age.”)

prohibitively expensive to many low and middle-income women who do not qualify for Medicaid.<sup>34</sup> Less than one half of the insurance plans offered in the United States provide coverage for contraception.<sup>35</sup> However, throughout the course of the Clinton Administration, federal funding for family planning skyrocketed. Much of this funding supports education about and distribution of contraception to the poorest segment of society. While such funding may be decreased by the current, anti-abortion Bush Administration, the increases in funding between 1992-2000 may have allowed the poorest Americans the greatest access to contraception, precisely what Sanger sought to achieve over five decades earlier.

#### **b. The technology of the Pill**

At the time of the Pill's development, actual scientific research into the female reproductive system was fairly recent, but it had been discovered that two groups of hormones were essential to female reproduction. The first, estrogen, is produced in the ovaries and produced the lining of the uterus in preparation for pregnancy. The second, progesterone, is produced in the *corpus luteum* and served to regulate pregnancy and the menstrual cycle.

Early research had shown that progesterone could be used to create temporary sterility.<sup>36</sup> Progesterone could be used to block ovulation and estrogen to regulate bleeding and cause a menstrual period each month.<sup>37</sup> The premise of an oral contraceptive was to alter the hormonal levels of estrogen and progesterone in the body such that they met the levels that occur during pregnancy. Thus the body would be fooled into considering

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<sup>34</sup>See Kathryn Kraft Leonhardt, Contraception in the New Millennium (posted 8/2000) <<http://www.abestesiologynews.com/wworks/CHARTS/contra/text/intro.html>>.

<sup>35</sup>See *id.* Half of all fee-for service plans do not cover any form of reversible contraception and only fifteen percent cover the five most common forms. Among health maintenance organizations, thirty-nine percent cover the five most common forms of contraception: oral contraception, diaphragms, IUDs, injectables, and implants. Brown, at 36.

<sup>36</sup>See Djerassi, *This Man's Pill* at 16. In 1919, Ludwig Haberlandt, Professor of Physiology at the University of Innsbruck in Austria undertook a critical experiment in which he implanted the ovaries of a pregnant rabbit into another rabbit who was not pregnant. The rabbit that had received the ovaries was then infertile for several months, suggesting that the introduction of the hormone of pregnancy, progesterone, could have a contraceptive result.

<sup>37</sup>See Asbell at 149.

itself pregnant and not allow any further fetal implantation in the uterus.

The availability of progesterone to use in the Pill was one of the most technologically difficult aspects of its development. Extracted progesterone was scarce and already in demand for preventing miscarriages and treating menstrual cramps.<sup>38</sup> Pincus needed a synthetic source of progesterone if the oral contraceptive were to be mass-produced, but while progesterone had been synthesized since 1935 it could not be used orally and large scale hormone synthesis was in its infant stages.<sup>39</sup> At the time, one researcher who had been successful in producing large quantities was Russell Marker at the Syntex Corporation in Mexico. Marker had traveled throughout the U.S. in search of a vegetable source to yield progesterone. He found that the plant cholesterol known as sapogenin could be heated in a sealed container to produce a chemical that was easily converted to progesterone. Marker discovered that the best source from which to extract the cholesterol was a non-edible yam found in Mexico. Carl Djerassi then built upon Marker's work to modify the synthetic progesterone, resulting in a form of progesterone eight times as potent as the natural hormone.<sup>40</sup> The resulting compound, norethindrone, was licensed to Parke-Davis & Co and approved by the FDA in 1957 for the treatment of menstrual disorders, but not as an oral contraceptive.<sup>41</sup> Concurrently with the Syntex development of norethindrone, Pincus, in association with G.D. Searle, was pursuing the use of a very similar compound, norethynodrel which was approved for menstrual regulation in 1957 and contraception in November 1959 under the name, Enovid, the world's first oral contraception.<sup>42</sup> Three years later the Parke-Davis compound, marketed under the name Ortho Novum, was approved by the FDA for use as contraception.<sup>43</sup> Ortho Novum had been delayed in human trials due to side effects not experienced in trials of

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<sup>38</sup>See *id.* at 18.

<sup>39</sup>See Djerassi, *This Man's Pill* at 19.

<sup>40</sup>See Asbell at 109.

<sup>41</sup>See Djerassi, *This Man's Pill* at 52.

<sup>42</sup>See *id.* at 53.

<sup>43</sup>See Egon Diczfalussy, *The Contraceptive Revolution* 32 (1997).

Enovid.<sup>44</sup> <sup>45</sup> Since the Pill's introduction, new pill regimens have been introduced using biphasic and triphasic models, which vary the progesterone/estrogen ration throughout the cycle. A variation of the Pill containing only progesterone is also available.<sup>46</sup>

c. Steroid contraception in the wake of the Pill: The FDA changes the rules

Less than a decade after oral contraception had entered the market, the climate in pharmaceutical research and development underwent a dramatic shift. At the time the pill was developed, general public attitudes were positive and encouraging of drug development, stemming from the lauded innovation of chemotherapy. However, in 1962, in the wake of the thalidomide tragedy in Europe and new public pressures to ensure the safety of pharmaceuticals, the FDA increased its participation in research and development, especially in cases that involved pregnancy.<sup>47</sup> Previously, the FDA's role was limited to enforcing safety requirements for drugs that were distributed to the public. Under the Kefauver Amendments, this mandate was expanded to regulating the efficacy of drugs as well. As a result, the FDA took on the additional responsibility of monitoring the clinical trials of all drug development.<sup>48</sup>

During the same period in which the general role of the FDA was expanding, high reporting of side effects and

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<sup>44</sup>See Asbell at 133.

<sup>45</sup>See Diczfalusy at 122. Following its successful introduction, the Pill has undergone modification in dosage level and composition. Early forms of the Pill contained a much higher hormone concentration than those used today. Because a failure of the Pill at the time it was in clinical trials would have been potentially politically disastrous, high concentrations were maintained as to avoid unwanted pregnancies. However, over time, the concentration has been lowered, thereby reducing the occurrence of side effects to be discussed *infra*.

<sup>46</sup>See *id.* The progestogen-only pill produces the side effect of breakthrough bleeding and thus its use is limited in most cases to nursing mothers, for whom the combination oral contraceptive (COC) is not prescribable.

<sup>47</sup>See Carl Djerassi, *The Politics of Contraception* 69-75 (1981). See also, Brown. at 4. (Noting that thalidomide, although never approved by the FDA or distributed in the United States, was in the process of clinical trials in the U.S. when signs of associated birth defects arose. This helped drive the FDA towards more involvement in the research process.)

<sup>48</sup>See *id.* During the clinical trials phase of drug development, humans are given the drug under investigation. In order to conduct such trials, the research entity must receive an Investigative New Drug (IND) exemption, which involves describing to the FDA the specific protocols to be used. There are three clinical phases before the FDA will allow a drug onto the market. The first, phase I, is a small-scale test to determine whether there are any unexpected responses to the drug that were not discovered during animal trials. Phase II is at an expanded scale and primarily is the period in which an effective dose is determined. Finally, in phase III, broader studies are conducted to detect any long-term or rare side effects of the drug. (Phase IV occurs after the drug has been approved, and includes further clinical trials.) (See Table 1.)



increasing public concern arose over the actual safety of the Pill led the FDA to create specific requirements for the development of steroid contraceptives. Of particular concern were possible links between the Pill and cervical cancer.<sup>49</sup> Therefore, in 1969, the FDA set specific parameters for the animal trials to be conducted prior to the clinical phases. (Table 1 provides a summary of the testing phases of steroid contraceptives) Under the FDA requirements, contraceptives must undergo testing in the rat, beagle, and monkey models.<sup>50</sup>

**Table 1**

**Food and Drug Administration requirements for animal toxicological studies for steroid contraceptives, estrogens, and progestogens<sup>51</sup>**

Clinical Study	Requirements
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<sup>49</sup>Much of this fear has been alleviated as hormone dosage levels have been reduced. Other noted side effects include increased incidence of blood clots or stroke. However, studies have shown that the Pill may reduce the chance of breast cancer diagnosis. See, e.g. Diczfalusy at 77-79. General side effects still associated with the Pill include an increased incidence of blood clots, stroke, and respiratory disorders, and the chance of such side effects occurring are increased among Pill users who smoke. See also, Brown. at 26-27. (noting that in the late 1960s, several non-scientific sources suggested a link between oral contraceptives and birth defects. However, no scientific research ever confirmed the link.) See also *infra* pgs. 26-27.

<sup>50</sup>See Carl Djerassi, *The Politics of Contraception* at 69-75. In most other drug categories, investigators may choose the species used for animal studies.

<sup>51</sup>*Id.* at 74. (Citing E.I. Goldenthal. FDA Papers. November 1969, at 15.)

IND phase I (lim- ited to a few days for up to 10 days' ad- min- is- tra- tion)	90- day stud- ies in rats, bea- gles, and mon- keys.
IND phase II (approximately 50 subjects for 3 menstrual cycles)	1-year studies in rats, beagles, and monkeys.

IND phase III (clin- i- cal tri- als last- ing sev- eral months or years de- pend- ing on the drug)	2- year stud- ies in rats, bea- gles, and mon- keys. Ini- ti- a- tion of 7- year stud- ies in bea- gles and 10- year stud- ies in mon- keys prior to start of phase III. Re- pro- duc- tion and ter- a- to- log- i- cal stud- ies in two species.
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NDA (New Drug Application)	No further requirements, but must include up-to-date progress reports on long-term studies in beagles and monkeys.
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Rodents are a typical model for early animal trials because of their relatively short life spans. Monkeys are also common for late-stage animal trials because of their close resemblance to humans. However, it was the beagle, chosen because of the amount of pharmacological background data available and because it was shown to produce tumors from hormone exposure<sup>52</sup> that proved to be a major influence on further contraceptive R&D. Due to the fact that the beagle undergoes only two (instead of monthly) ovulatory cycles annually and other pathological divergences, the choice of the beagle as the third species for animal trials resulted in significant delays and added costs for drug development.<sup>53</sup>

Species	Urine (%)	Feces (%)	Plasma half-life (hours)
Man	94	1-2	14
Rat	90	2	4-6
Guinea pig	90	5	9
Beagle	29	50	23-35
Rhesus Mon-key	90	2	2-3
Capuchin monkey	45	54	20
Stump-tail mon-key	40	60	1
Mini-pig	86	1-2	4-7

<sup>52</sup>See Alexander Jordan, FDA Requirements for Nonclinical Testing of Contraceptive Steroids, 46 Contraception 499 (Dec. 1992).

<sup>53</sup>See Carl Djerassi, The Politics of Contraception at 75. (Citing Carl Djerassi, Birth Control After 1984, 169 Science 941-51 (1970).)

Table 2

Data on excretion patterns and plasma half-life for an experimental drug

Excretion

Note that among the common animal models listed, the beagle differs most from man in terms of drug excretion and plasma half-life.

See also Djerassi, *This Man's Pill* at 284. "But worst of all, the pharmaceutical industry, faced with the loss of a significant portion of the 17-year patent life of a drug and hence its proprietary position by undertaking such prolonged studies. [There was no patent term restoration for pharmaceuticals at the time] Under these conditions, only drugs capable of commanding extremely high prices over their shortened patent life would be likely to return what the industry (though perhaps not society at large) would consider an acceptable profit." (See Table 2, footnote 46.) In 1987, the World Health Organization's Special Programme of Research, Development and Research Training in Human Reproduction revised the guidelines for animal testing of contraceptives, reducing the length of time for testing in beagles.<sup>54</sup> WHO tests had shown that virtually all progesterone exposure above a minimal dose induce tumors in beagles.<sup>55</sup> Soon after, in 1989, the FDA revised its guidelines even further, eliminating the required beagle studies.<sup>56</sup> (See Table 3 for the current testing requirements.) Furthermore, the new regulations allowed for deviation from the delineated requirements "provided that there is a strong scientific rationale."<sup>57</sup>

**Table 3**  
**Current Testing Requirements for steroid contraceptives<sup>58</sup>**

Clinical Phase	Type and Duration of Preclinical Studies
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<sup>54</sup>See Jordan at 499-503.

<sup>55</sup>See Diczfalusy at 34.

<sup>56</sup>See Brown at 38.

<sup>57</sup>See Jordan at 508.

<sup>58</sup>See *id.* at 501.

I	Single dose studies in rats and mice. Repeat dose studies in rats and monkeys of a minimum dose of one month.
II	Flexible, with a duration at least equal to the length of the proposed clinical trial to a maximum of 6 months (rat) or one year (monkey) Special studies of reproduction and return to fertility should be performed prior to the initiation of clinical trials in women who are at risk for pregnancy.

III	Same as for phase II. Re- sults of geno- tox- i- c- ity tests should be sub- mit- ted prior to phase III.
NDA	6-month toxicology (rat) 12-month toxicology (monkey) 2-year carcinogenicity (rat/mouse)

d. Contraception development under the stricter FDA regime

Three different delivery systems were developed during the period of heightened FDA regulation: injectables, emergency contraceptives, and abortifacients. The development of each system occurred during the stricter period, but none received FDA approval until the regulations of 1969 were replaced in 1989.

1. Depo-Provera

**Depo-Provera is an injectable progestin contraceptive with a three-month duration and a lower failure rate than that found in oral contraception.**<sup>59</sup> While producers submitted Depo-Provera to the FDA in 1967<sup>60</sup> and it was approved abroad by the early 1970s<sup>61</sup>, the FDA did not approve Depo-Provera until 1992.<sup>62</sup> WHO studies found no significant incidence of side effects compared to oral contraceptives<sup>63</sup>, but the FDA denied the new drug application, citing an insufficient basis for determining that Depo-Provera was safe in long-term users.<sup>64</sup><sup>65</sup> Approval occurred after the FDA requirement of beagle trials had been lifted. Currently Depo-Provera is used by 15% of women between the ages of fifteen and seventeen who are using contraception.<sup>66</sup> It has a lower annual cost than any other reversible contraception with the exception of contraceptive implants, to be discussed infra. Due to a high incidence of breakthrough bleeding, however, its one-year continuation rate is the lowest among steroid contraceptive options. Furthermore, it has been found that fertility may regularly take

<sup>59</sup>See Elizabeth C. McGuffey, Contraceptive Options for the 1990s, *Journal of the American Pharmaceutical Association*, March-April 1997, at 150. The failure rate for injectable progestins is approximately 0.0-0.30% compared with 0.0-3.00% for combination oral contraceptives and 1.1-3.00% for progestogen-only oral contraceptives. (See Table 4 for a complete listing of first-year failure rates of the most common contraceptive methods.)

<sup>60</sup>See *id.* at 500.

<sup>61</sup>See Djerassi, *The Politics of Contraception* at 155. By 1979, although not approved in the U.S., Depo-Provera was in use in 60 other nations. Depo-Provera was approved in the U.S., by 1979, however, for the treatment of endometrial cancer.

<sup>62</sup>See McGuffey, at 151.

<sup>63</sup>See *id.* However, like other progestogen-only contraceptives, there is a higher incidence of break-through bleeding and weight gain than found with combination contraceptives.

<sup>64</sup>See Diczfalusy at 78. WHO testing did find a slightly elevated relative risk of invasive cervical cancer in long-term users (2.0) and a possible increase in occurrence of breast cancers, but no greater risk than found with oral contraceptives.

<sup>65</sup>The FDA also found an increased occurrence of mammary tumors in beagles exposed to Depo-Provera. See Jordan at 500.

<sup>66</sup>See Leonhardt.



as long as eighteen months to resume.<sup>67</sup>

## 2. Emergency Contraception

Emergency or post-coital contraception (also known popularly as the morning after pill) utilizes high doses of oral contraception within 72 hours of intercourse to inhibit embryo implantation.<sup>68</sup> The administration of emergency contraception has occurred under the name the “Yuzpe protocols” since 1974.<sup>69</sup> The FDA approved the off-label use<sup>70</sup> of oral contraceptives for use post-coitally in 1995. As an off-label protocol, prescribing doctors had to open and re-package oral contraceptives for patients requiring post-coital contraception since there was no independent manufacture of oral contraceptives packaged for emergency use.<sup>71</sup> Responding to widespread use of the protocol, the FDA took the “unusual step” of requesting that manufacturers of oral contraceptives submit supplemental new-drug applications for the use of their products as emergency contraceptives. In 1997, the first specifically manufactured emergency contraception kit, Preven, entered the market and was followed in 1999 by a second kit, Plan B.<sup>72</sup> Plan B utilizes progestogen-only protocol that has proven to have a lower incidence of nausea and higher efficacy. Neither kit has been shown to disrupt an already-existing pregnancy. The kits have been granted a pseudo-over-the-counter status in the state of Washington, and have been proposed for such status in the state of New York.<sup>73</sup> Similar programs

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<sup>67</sup>See Stacey Schultz, The pill has company: the patch, the ring, the shot, U.S. News and World Report 58 (April 2, 2001).

<sup>68</sup>Emergency contraceptives are nearly 100 percent effective within the first twelve hours after intercourse and then proceed to decline as time since intercourse passes. See David Gilden, No Rx required, The Village Voice, April 10, 2001, at 45-46.

<sup>69</sup>See Djerassi, This Man's Pill, at 74. The protocol is named for Canadian Professor A. Albert Yuzpe, who was the first to publish a study of emergency contraceptives showing them to be safe and effective. See also, Emergency Hormonal Contraception, A Short History (1998) <<http://www.plannedparenthood.org/library/BIRTHCONTROL/EmergContraHistory.htm>>.

<sup>70</sup>Off-label use involves prescribing a drug for treatment of an ailment that is not included on the FDA package insert or varying the dosage applied for a listed ailment. Brown, at 14. A study by the American Medical Association estimated that of the 2.1 billion prescriptions written in the U.S. annually, forty to sixty percent are prescribed for off-label use. Michelle Lynn Lakomy, A Meaningful Choice: Two FDA Approved Drugs are Combined to Perform Medical Abortions, 18 Women's Rights Law L. Rep. 49, 56(1996).

<sup>71</sup>See Dorothy L. Pennachio, New Approaches to Emergency Contraception, Patient Care 19-37 (March 15, 2001) <<http://proquest.umi.com...>>.

<sup>72</sup>See Leonhardt. Preven and Plan B have been demonstrated to reduce the risk of pregnancy by 75%-85%, respectively.

<sup>73</sup>See Gilden at 45-46. Gilden refers to NY A.B. 9653, 225<sup>th</sup> Leg. (N.Y. 2002). The bill states:

have been instituted in France and the United Kingdom.

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Section 2. Legislative findings. The legislature finds that the United States Food and Drug Administration (FDA) has declared emergency contraceptive pills to be safe and effective in preventing pregnancy when used within 72 hours after unprotected intercourse. The legislature further finds that the American College of Obstetricians and Gynecologists and the American College of Nurse-Midwives support the availability of over-the-counter access to emergency contraception. Yet, until the FDA approves such access, the legislature deems it essential to create a simple structure for approximating over-the-counter availability with appropriate professional safeguards, while respecting the prescribing scopes of physicians, nurse practitioners, and midwives, the treating and case-finding scope of practice of registered professional nurses, and the dispensing scope of practice of pharmacists. Nothing in this act shall be deemed to alter the scopes of such professions.

### 3. Abortifacients: RU 486

Possibly the most controversial contraceptive to date, RU 486 (mifepristone) is an anti-progestational agent which functions by itself as a contraceptive or when combined with prostaglandin, a substance that stimulates uterine contractions, can chemically induce abortion.<sup>74</sup> <sup>75</sup> The drug must be administered within the first 49 days of pregnancy, and use of the drug involves a multi-step process over three weeks.<sup>76</sup> Approved in France and elsewhere in Europe, the drug was made an FDA-banned import in 1988, thereby preventing any U.S. clinical or animal trials.<sup>77</sup> In 1993, the Clinton Administration instructed the FDA to limit the import ban on RU 486, and its patent-holder, Hoechst-Roussel, licensed the technology to the Population Council. The Population Council filed a New Drug Application and was granted a conditional approval in 1996 that was made final in 2000 upon compliance with FDA requirements and obtaining a manufacturer for the product.<sup>78</sup> Reported side effects do include nausea, heavy bleeding, and cramping.<sup>79</sup> Due to its recent approval, statistics are not available regarding the extent of use of RU 486 in the U.S., but use thus far seems light, and only 1% of general practice physicians and 6% of gynecologists prescribe the drug.<sup>80</sup> Since its introduction in France, more women have chosen to seek abortions earlier in their pregnancies, but there

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<sup>74</sup>See Djerassi, *This Man's Pill*, at 84-85.

<sup>75</sup>RU 486 was not the first abortifacient to reach the U.S. Prior to the RU 486 controversy, physicians in the U.S. were using a combination of injected methotrexate, a cancer drug, and misoprostol, used to treat ulcers, to achieve the same effect as RU 486. Unlike RU 486, which was FDA approved for its abortifacient use, the methotrexate-misoprostol combination was an off-label use of the two drugs. See Lars Noah, *A Miscarriage in the Drug Approval Process?: Mifepristone Embroils the FDA in Abortion Politics*, 36 *Wake Forest L. Rev.* 571 (2001). See also Lakomy, at 56. Off-label use is not regulated by FDA requirements for testing. Therefore, manufacturers cannot advertise products for their off-label uses to consumers or physicians.

<sup>76</sup>See Nancy Gibbs, *The pill arrives*, *Time* 40-49 (Oct. 9, 2000) <<http://proquest.umi.com...>>. A woman is first tested to determine the stage of her pregnancy. If she is found to be within the first 49 days of pregnancy, she is given mifepristone. Two days later she is given misoprostol to cause contractions and expel fetal tissue. After twelve days, the woman is examined to determine that the abortion has been successful.

<sup>77</sup>See James G. Dickinson, *Mifeprex: FDA's first 'political' drug approval*, *Medical Marketing and the Media* 14-20 (Nov. 2000) <<http://proquest.umi.com...>>.

<sup>78</sup>See id. The original manufacturer contracted to produce RU 486 for U.S. distribution, Gideon Richter of Hungary, backed out of the arrangement and was subsequently replaced with an unnamed Chinese manufacturer. See also Silverberg at 1570-1571. (Describing the import alert as an internal memorandum circulated by the FDA to field and Customs agents advising agents of "new or unusual problems affecting imports. Silverberg notes that while most import alerts provide reasons for the alert and instructions with regard to an automatic detention, import alerts for abortifacients have included no such reasons while instructing the abortifacients be denied entry into the U.S.)

<sup>79</sup>See Gibbs.

<sup>80</sup>See Sara Rimensnyder, *Weak Choice, Reason* at 14 (Feb. 2002).

has not been a significant change in the abortion rate.<sup>81 82</sup>

#### **e. Current options in steroid contraception**

In addition to those methods discussed *supra*, which came to market only after considerable controversy, a variety of hormonal contraceptives based on a range of delivery systems are currently available. A number of the current options are discussed in this section. The discussion is meant to be a general summary of the products on the market, and it avoids most technical aspects of the given delivery systems. While complete information is not available for all methods, Table 4 provides a listing of known failure rates for the given methods. Also to be discussed are the side effects and benefits associated with each form. Most of these methods became available only after a 1995 study, which examined the percentage distribution of different forms of contraception, where hormonal contraceptives comprised less than thirty percent of all contraceptive use.<sup>83</sup> (See Table 5) While non-hormonal vaginal inserts, condoms, spermicides, and IUDs are outside the scope of this paper, it is important to note their prevalence among contraceptive users. It remains to be seen whether the new products on the market will lead to a higher proportion of use of steroid contraception. It may be expected that some of the spermicide products inserted vaginally will be replaced with some of the new delivery systems such as the vaginal ring or the hormonal patch.

**Table 4**

#### **First Year Failure Rates of Contraceptive Methods<sup>84</sup>**

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<sup>81</sup>See Kathryn Moore, At Last! The FDA Approves Mifepristone, Reproductive Health Technologies Project (2001) <[http://www.rhttp.org/news\\_archive/news\\_early\\_atlast.htm](http://www.rhttp.org/news_archive/news_early_atlast.htm)>.

<sup>82</sup>For Further analysis of the impact of RU 486 on contraceptives, see *infra*, p 37.

<sup>83</sup>See Leonhardt.

<sup>84</sup>McGuffey at 150. (Citing R. Ruggiero, *Contraception* in L.Y. YOUNG AND M.A. KODA-KIMBLE, EDS. APPLIED THERAPEUTICS: THE CLINICAL USE OF DRUGS 1-26 (1995); and L. Parent-Stevens and D.L. Lourwood, *Contraceptive methods and products* in T.R. COVINGTON, R.R. BERARDI, L.L. YOUNG, ET AL. HANDBOOK OF NON-PRESCRIPTION DRUGS 113-32 (1996).

Contraceptive Method	Failure Rate Range (%)*
Subdermal pro-gestin im-plant	0.0-0.04
Tubal sterilization	0.0-0.40
Injectable pro-gestin	0.0-0.30
Combination oral contraceptive	0.0-3.00
NuvaRing	Unknown —  1.0-2.0 <sup>85</sup>
Progestogen-only contraceptive	1.1-3.00
Intrauterine device	0.5-3.00
RU 486	2.0-4.0
Male condom	4.2-12.0
Female condom	5.0-25.0
Diaphragm with spermicide	2.1-18.0
Cervical cap	8.0-18.0
Spermicidal products	0.3-21.0
Rhythm method & other natural methods	2-14.4-20.0
Emergency Contraceptives	Unknown – 15-25.0
None	43.1-85.0

\* The lower number represents predicted or observed failure rate with optimal use; the higher number represents failure rate with typical use.

<sup>85</sup>Emil Vernarec, Hormonal vaginal ring provides once-monthly contraceptive, RN 94 (Jan. 2002).

Table 5

Percentage Distribution of Current Contraceptive Methods\*<sup>86</sup>

Method	%
Female ster- il- iza- tion	27.7
Oral Contraception	<b>26.9</b>
Male Con- dom	20.4
Vasectomy	10.9
Withdrawal	3.0
Periodic Abstinence	2.3
Diaphragm	1.9
Other	1.8
Implant	<b>1.3</b>
IUD	0.8

\* 1995 data, respondents ages 15-44; "Other" includes douche, sponge, jelly, or cream alone. Boldface indicates hormonal contraceptive.

## 1. Implants: Norplant and Norplant-2

Norplant, the first implanted (non-IUD) contraception system consists of six subdermal levonorgestrel implants that provide five years of contraception.<sup>87</sup> After an initial stabilization period,<sup>88</sup> the implants deliver a consistent daily dosage of the contraceptive with a high efficacy over the entire five-year use period. Fertility is restored within 24 to 96 hours of implant removal.<sup>89</sup> Users experience the bleeding irregularities associated

<sup>86</sup>See Leonhardt.

<sup>87</sup>See McGuffey at 152.

<sup>88</sup>See Diczfalusy at 79.

<sup>89</sup>See McGuffey at 152.

with all progestogen-only systems. Continuation rates are fairly high, with a rate of 88% after one year<sup>90</sup> and 49% after four years.<sup>91</sup> However, significant litigation has arisen with respect to complications in insertion and removal of the implants, leading to a settlement of claims by Norplant's manufacturer, Wyeth-Ayerst, in 1999.<sup>92</sup> In response to insertion and removal difficulties, Norplant-2 was developed, utilizing two instead of six implants. This system delivers an equivalent daily dose of hormone as Norplant and lasts up to six years.<sup>93</sup> There are several other implanted contraceptives currently in development including a single rod system similar to Norplant and Norplant-2, a single capsule that biodegrades once it is no longer effective (thereby eliminating many removal difficulties), and several other progestogen-only implant systems.

## 2. Injectables

One of the most recently approved contraceptive systems is a monthly injectable contraceptive marketed under the name Lunelle.<sup>94</sup> Lunelle is a combined contraceptive, and thus has less breakthrough bleeding than found in progestogen-only systems, reports have indicated higher incidence of breakthrough bleeding than in combination *oral* contraceptives.<sup>95</sup> No other side effects were reported to be more common than in combination oral contraceptive use with the exception of a possible, but not statistically determined weight gain. Fertility has been found to resume within two to four months.<sup>96</sup> Other injectables currently in development include two and three month formulations of both progestogen-only and combination varieties.<sup>97</sup>

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<sup>90</sup>See Leonhardt.

<sup>91</sup>See Diczfalusy at 79.

<sup>92</sup>See Leonhardt. See also D.K. Wyisiwski and L. Green, Serious adverse events in Norplant users reported to the Food and Drug Administration's MedWatch Spontaneous Reporting System, 85 *Obstetrics and Gynecology* 318-320 (April 1995). (Finding no significant increase in stroke, but elevated incidence of benign intra-cranial hypertension and thrombotic thrombocytopenia purpura. Such statistical findings were made based upon reporting rather than prescribing rates. (See also the subsequent comments to Wyisiwski & Green's study by Chez and Siving in the following two issues, respectively, disputing the data with regard to incidence of side effects has been disputed with regard to consideration of under-reporting. )

<sup>93</sup>See Diczfalusy at 80.

<sup>94</sup>See Anonymous, Position Paper on the Monthly Contraceptive injection Lunelle, *Network News* 6-7 (May-June 2001). Lunelle was approved by the FDA in October 2000. Lunelle is available internationally under the names Cyclofem and Cyclo-Provera.

<sup>95</sup>See *id.* Users reported a thirty percent rate of breakthrough bleeding after one year as compared to seventeen percent in combination oral contraceptive users.

<sup>96</sup>See Schultz at 58.

<sup>97</sup>See Diczfalusy at 78-79.

Developers of the new injectables aim to solve the problem that leads to the majority of discontinuation, breakthrough bleeding.

### **3. Contraceptive rings**

Vaginal rings, which may be inserted and removed by the user provide a contraceptive effect through a steady release of a low dosage of hormones.<sup>98</sup> Dosages are lower than in any implant, injectable, or oral system since the contraceptive does not encounter the liver before delivery. Development is underway in both progestogen-only and combined ring forms. The FDA recently approved the first of these rings for market, a monthly combination ring sold under the name NuvaRing.<sup>99</sup> The NuvaRing is inserted at the start of the cycle and is left in place for three weeks, followed by a week without the ring during which time the user will experience a menstrual period.<sup>100</sup> Side effects are similar to those associated with combination oral contraceptives with the additional possible of vaginal discharge, vaginitis, or irritation.

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<sup>98</sup>See *id.* at 80-81.

<sup>99</sup>See Vernarec at 94.

<sup>100</sup>See FDA Approves First Hormonal Vaginal Contraceptive Ring, FDA Talk Paper, T01-46 (October 3, 2001).



#### 4. Contraceptive patch

A single transdermal patch delivering a combination contraceptive, Ortho Evra, has been approved by the FDA.<sup>101</sup> The waterproof patch provides a weekly dose of contraception and is applied on the same day each week for three consecutive weeks, followed by a fourth, patch free, week. While largely effective, the patch is less effective in women weighing over 198 pounds and may cause mild skin irritation. Otherwise appears to have side effects comparable to combination oral contraceptives.<sup>102</sup> A second transdermal patch is currently in clinical trials.<sup>103</sup>

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<sup>101</sup>See Joanne E. Chatfield, FDA Approves weekly birth control patch, 65 American Family Physician at 326-329 (Jan. 15, 2002).

<sup>102</sup>See FDA Approves First Hormonal Contraceptive Skin Patch, FDA Talk Paper, T01-58 (November 20, 2001).

<sup>103</sup>See FDA okays Berlex Drug, Chemical Market Reporter 13 (May 21, 2001).

## II. Political and Economic Barriers: How FDA Policy is Shaped and Its Subsequent Effects on Contraceptives Research and Development

The options discussed in the previous section do provide a menu of steroid contraception available in the United States, but most of the methods described rely upon variations of the original oral contraceptives and do not represent notable scientific progress. The greatest strides have occurred in the delivery systems for the contraceptive, while the actual pharmacological components have not changed much. Many factors contributed to the fairly stagnant arena of contraceptives research and development, marked most visibly by a withdrawal from contraceptive R&D among most major American pharmaceutical developers. Prior to 1980, nine of the major pharmaceutical companies in the U.S. conducted contraceptives research, today, only one major U.S. pharmaceutical producer continues to conduct contraceptives research.<sup>104</sup> A study in 1988 found that contraception is not even listed in the top 35 therapeutic categories of research and development.<sup>105</sup> By 1995, none of the eight largest pharmaceutical companies in the world were active in contraceptive R&D.<sup>106</sup> One factor contributing to the industry withdrawal is the association of contraception and abortion, a constant political liability for those who advocate contraceptive use and research. Such political opposition has led to inconsistent and often reduced public funding for contraceptive R&D. In addition, the high costs of product liability suits in the 1970s caused many manufacturers to leave the market and drove up the prices charged by those who stayed. High prices resulting from liability and strict FDA regulation of R&D

<sup>104</sup>See Carl Djerassi, *The Bitter Pill*, at 356. Only Johnson & Johnson, through its Ortho division, is actively involved in contraceptives R&D. See also Carl Djerassi, *Prognosis for the Development of New Chemical Birth-Control Agents*, 166 *Science* 468, 471 (1969). (Noting the withdrawal of major pharmaceutical companies from contraceptive R&D due to heightened FDA regulation of clinical trials)

<sup>105</sup>See *id.* at 360.

<sup>106</sup>See Carl Djerassi, *The Economics of Contraceptives R&D*, 272 *Science* 1858 (1996). See also, Sophia Cariaty and Rachel Meltzer, *The Battle for Birth Control*, *American Health For Women*, 54, 54 (Jan. 1999). (“The US is one of the few countries in the industrialized world that has not recently announced tremendous breakthroughs in contraception. A small market, risky lawsuits, the long and expensive FDA approval process, and the powerful anti-contraceptive-antiabortion movement all contribute to a lack of incentive on the part of the pharmaceutical industry when it comes to contraception research.”)

coupled by a lack of insurance coverage of contraceptives confined the market for those contraceptives already available, thus providing little incentives for the development of new methods.

The following pages discuss each of these problems and their causes and lay out possible ways to remedy the failing sector of technological advancement. First is a summary of the high costs of developing new contraceptive drugs due to regulation and tort liability, including an examination of an administrative defense as a partial solution. Next is a discussion of the political vulnerability of contraceptives research due to its link to abortion. Finally, a set of steps is provided that, if implemented, may serve to create sufficient incentives for greater contraceptives research and development.

#### **a. Costs of development**

The development of any new drug in the United States involves a tremendous investment of capital. Contraceptive drugs are no exception, rather, for the period of time when FDA had heightened regulation of contraception clinical trials, the costs of research and development for contraception was inflated beyond the costs of other drugs.<sup>107</sup> Much of the exodus from the contraceptive market occurred during the period of increased regulation, and the lifting of the requirements has not spawned a substantial return. Even after the FDA requirements were lifted, costs remained exorbitant. In 1997, it was estimated that a new contraceptive would cost \$250 million dollars to bring to market.<sup>108</sup>

Beyond the high costs associated with FDA compliance, product liability has also contributed to the research slowdown.<sup>109</sup> Product liability, resulting in costly litigation, has been a significant component of contraceptives research for almost as much time as the Pill has been on the market. Anecdotal reporting of severe side

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<sup>107</sup>See Djerassi, *The Bitter Pill* at 357.

<sup>108</sup>See Diczfalusy at 23.

<sup>109</sup>Product liability is tried most often under a theory of strict liability, so the manufacturer bears all the expense of adverse effects, regardless of any negligent behavior or intent and without any balancing with the benefits of the disputed product. See Brown, at 16. "Thus we all pay higher prices for products so that the manufacturer can purchase insurance to compensate those unfortunately injured by defective products."

effects of the Pill in its early forms created a public outcry that, in 1970, led to a Congressional investigation of the safety of steroid contraceptives.<sup>110</sup> Hearings before the US Senate Subcommittee on Monopoly of the Select Committee on Small Business led to the inclusion of inserts in every package of contraception detailing potential side effects of the Pill.<sup>111</sup> The hearings also lent legitimacy a series of lawsuits against contraceptives manufacturers that had already begun.<sup>112</sup> Few suits were decided in favor of the plaintiffs, but litigation costs were so high that many cases were settled during the late 1960s and 1970s. A 1982 report by the Office of Technology Assessment listed liability costs for oral contraception as the highest of any drug category.<sup>113</sup> While litigation decreased in the 1980s as epidemiological evidence credited the Pill with health benefits and lower dosage levels decreased the occurrence of side effects<sup>114</sup>, a consistent trickle of litigation has continued, resulting in some awards to plaintiffs and tremendous litigation costs regardless of a suit's outcome.<sup>115</sup>

One solution to the chilling effects on research created by constant and exorbitantly expensive litigation is an administrative exemption from product liability, often referred to as the "FDA defense" in cases of pharmaceutical torts. An exemption from liability for highly regulated products alleviates the cost burden and over-deterrence created by duplicative consumer protections, regulatory standards and tort liability.<sup>116</sup>

Such an exemption has been advocated by the American Law Institute.<sup>117</sup> The ALI's proposal allows an

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<sup>110</sup>See Djerassi, *This Man's Pill*, at 73.

<sup>111</sup>Some members of the medical community criticized the hearings and the resulting required package inserts as overly alarming and deterrent to steroid contraceptive use. See G.G. Liddle, *Birth Control by the FDA*, 212 *Journal of the American Medical Association* 159 (April 6, 1970). ("Because of the news coverage of Senator Nelson's hearings on the oral contraceptives, women have already been warned of the risks. As a result, thousands are said to have stopped taking the pills, and some unwanted pregnancies have been reported. . . . Some women of lively imagination who have never had any trouble while taking the pills, when they read [the package insert], are going to develop [one of the listed potential side effects] . . . [We] believe that [FDA] Commissioner Charles C. Edwards should leave the practice of medicine to physicians in practice.

<sup>112</sup>See Djerassi, *This Man's Pill*, at 75.

<sup>113</sup>*Id.*

<sup>114</sup>See *id.* at 77. Studies showed that oral contraception protected against ovarian and endometrial cancers and functional ovarian cysts.

<sup>115</sup>See Djerassi, *The Bitter Pill*, at 357.

<sup>116</sup>See Richard B. Stewart, *Symposium: Regulatory Compliance as a Defense to Products Liability*, 88 *Geo L.J.* 2167, 2169-2170 (2000).

<sup>117</sup>See *id.* at 2167-2169. (Citing American Law Institute, *Reporter's Study, Enterprise Responsibility for Personal Injury* (1991):

First, the risk must have been placed under regulatory control by a specialized administrative agency, a body with statutory authority to monitor and assess risk-creating activities in its area of responsibility, and with a mandate to establish and revise regulatory controls

exemption from tort liability in cases where agency regulation screens the public from unacceptable risk. Furthermore, the ALI notes that such a scheme would be more appropriate than tort liability since juries and judges are often poorly equipped to evaluate the complex and technical evidence associated with tort litigation, a factor clearly important in cases of healthcare and drug reactions.<sup>118</sup> Such an exemption is appropriate in the pharmaceutical field, where the FDA already takes an active role in screening safety and efficacy of drugs and requires significant disclosure and ongoing testing, even after drug approval. If adverse effects appeared after approval, the FDA already has the authority to remove a product from the market and issue warnings to consumers. Five states already allow an FDA defense in state court with regard to punitive damages.<sup>119</sup>

The FDA defense has been applied in another highly litigated area of the pharmaceutical industry: vaccinations.<sup>120</sup> The National Childhood Vaccination Act of 1986 creates a liability shield for producers of pediatric

on enterprise behavior. Under a system of regulatory screening, a risk or category of risks is placed under regulatory control after accurate up-to-date data on such risks are provided to the responsible agency by the enterprise or otherwise obtained by the agency; the data and risks are evaluated by the agency in accordance with authoritative criteria; clearance is granted upon a reasoned determination that the risk is acceptable; and there is an ongoing system of agency monitoring and review in place to deal with the new information or changed circumstances. Under a system of regulatory standards the criteria are essentially the same, except that the standards adopted must be intended to limit and must limit, directly or indirectly, the amount of such risks that may be generated. Second, the enterprise in question must have complied with all relevant regulatory requirements [such as those reporting and disclosure requirements imposed by the Federal Food, Drug, and Cosmetic Act].

Third, the defendant must have publicly disclosed to the relevant regulatory agency any material information in its possession (or of which it has reason to be aware) concerning the risks posed by the defendant's activities and/or the means of controlling them. This requirement would extend to information indicating that agency standards or tests may be inadequate or inappropriate. . . . But whether or not such requirements have been imposed by statute, the regulatory compliance defense would not be available as a matter of tort law if the defendant failed to report such information. . . .

These limitations are designed to ensure that liability can be invoked in cases where regulatory lag or other causes leave risks unregulated; where regulation is purely nominal; or where regulation is compromised because the agency does not have material information about risk and its assessment or control, but regulated firms do. These requirements also give regulated firms additional incentives to comply with regulation and to disclose to the agency information about regulatory inadequacy. . . .)

<sup>118</sup>See *id.* "Jury verdicts imposing tort liability in such cases have been directly contrary to regulatory determinations regarding product risks and benefits, as well as the overwhelming consensus of knowledgeable independent scientists regarding these products' potential to cause harm." See also Brown at 27-28. (Discussing *Wells v. Ortho Pharmaceutical Corp.*, 615 F. Supp. 262 (N.D. Ga. 1985), *aff'd*, 788 F.2d 741, *reh-g denied*, 795 F.2d 89 (11<sup>th</sup> Cir.) (en banc). *Wells v. Ortho* involved allegations that a spermicide produced by Ortho caused birth defects. In a bench trial, Judge Shoob found for the plaintiff in the face of overwhelming scientific evidence in favor of Ortho based upon his preference for the demeanor of the plaintiff's expert witnesses. While the judgment was reduced on appeal, the verdict was affirmed because the appellate court did not find the trial court ruling clearly erroneous.)

<sup>119</sup>See Brown, at 40.

<sup>120</sup>See Djerassi, *The Bitter Pill*, at 360.

vaccines. Like contraceptives, vaccines are highly susceptible to litigation since both are administered to healthy people. Therefore, tolerance of side effects is much lower than in cases where a drug is administered to a person who is already ill, leading to greater instances of litigation and higher jury awards based on less severe injury than awards for injury resulting from other types of pharmaceuticals.<sup>121</sup> This low tolerance was undoubtedly further exacerbated in the case of vaccinations since recipients are children.<sup>122</sup>

It is important to note that the primary goal of the National Childhood Vaccination Act was availability of the protected vaccines, not research and development of new vaccines.<sup>123</sup> While the goal of availability was met, the defense did not lead to considerable development of new vaccines. This is largely due to the limited market for vaccines and the fact that only the typical childhood diseases required in most states are included in liability protection. This is also partially true of contraception.<sup>124</sup> In the current state of healthcare, which lacks insurance coverage for most contraception, the market for contraceptive sales is limited.<sup>125</sup> However, full insurance coverage would broaden the contraception market to include populations unable or unwilling to afford steroid contraceptives out-of-pocket.<sup>126</sup> In addition, unlike vaccines, where one vaccine per disease is likely to be sufficient for an entire market, one or a few contraceptives are not sufficient to reach entire potential market. The availability of a greater variety of steroid contraceptives could expand the consumer base.

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<sup>121</sup>See *id.*

<sup>122</sup>In contrast with childhood vaccines, the healthy people argument may be in part counterbalanced by a certain societal attitudes towards intercourse and the use of contraceptives as a facilitator of intercourse outside of marriage.

<sup>123</sup>See Brown, at 45.

<sup>124</sup>See *id.* at 36-37.

<sup>125</sup>"The massive need [for new forms of steroid contraception] may well exist, but not the potential market . . . The pharmaceutical market, which has changed dramatically during the past decade, has spoken. It now focuses on blockbuster drugs dealing with diseases of aging or deterioration in the increasingly geriatric populations of affluent Japan, North America, and Europe. . . ." Carl Djerassi, *The Economics of Contraceptives R&D*, at 1858.

<sup>126</sup>See Brown, at 37. Brown also argues that contraceptives be re-classified to fall under the Orphan Drug Act, a product of the Reagan Administration that provided incentives to pharmaceutical companies to research drugs that had a low profit potential because they applied to fairly narrow population groups. Contraceptives have much broader potential market than populations targeted by orphan drugs, and therefore do not require such significant subsidy. Expanding insurance coverage will relax the artificial constraints on the contraceptive market, and coupled with curbs on liability, will provide the financial incentives necessary to spur more contraceptives R&D. A component of the Orphan Drug Act incentive package, namely the seven-year market exclusivity, would run contrary to objectives sought here. Exclusivity of a particular product will be covered under patent protection; beyond that, variety is sought in the contraceptives market, not further constraint of options.

An FDA defense for contraceptives would, as was the case with vaccinations, *de facto* acknowledge the inherent risk of steroid contraceptives. This is not unreasonable, for no drug approved by the FDA would qualify as completely free from risk.<sup>127</sup> Rather, those drugs and medical devices approved by the FDA are the result of a balancing or risk analysis that takes into account the purpose of the particular drug or device. Such balancing allows for greater tolerance of adverse side effects in cases of dire medical need and less tolerance in cases of milder disorders or market substitutes.<sup>128</sup> Thus, the healthy person argument is already built into FDA approval analysis.

#### **b. Abortion's impact on contraception**

The history of contraception provided in Part I, *supra*, notes the political association of contraception and abortion throughout the Pill's existence. Abortion politics have often stood in the way of contraceptives research and development through funding policies and through influence upon the FDA. A deeper investigation of the rocky approval process of RU 486 will demonstrate the FDA's responses to the abortion politics of those in positions of power in the U.S. Such vacillations in the political wind are especially significant as advances in technology blur the discreet lines between contraception and abortion, potentially shifting the legal standing of both.

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<sup>127</sup>See Brown, at 7.

<sup>128</sup>See *id.* at 17. Citing the Restatement (Second) Torts §402A, Comment k (1965). Comment k" addresses "unavoidably unsafe products" and was utilized in the argument for the Childhood Vaccination Act and would be most likely be considered in the case of an FDA defense for contraceptives:

Since the disease itself invariably leads to a dreadful death, both the marketing and the use of the vaccine are fully justified, notwithstanding the unavoidable high degree of risk which they involve . . . The seller of such products, again with the qualification that they are properly prepared and marketed, and proper warning is given, where the situation calls for it, is not to be held to strict liability for unfortunate consequences attending their use, merely because he has undertaken to supply the public with an apparently useful and desirable product, attended with a known but apparently reasonable risk."

See also Stewart at 2172. ("While vaccines did cause serious side effects in a small subset of recipients, juries and courts did not consider whether the benefits gained from mass vaccination outweighed the costs imposed. Such failures reflect a systemic limitation of tort litigation, which relies on uncoordinated, case-by-case decision making [sic] by ad hoc juries.")

## 1. RU 486 Revisited

RU 486 stands at the crossroads between contraception and abortion, and accordingly, it has served as a litmus test for the political climate of both since it entered the arena of U.S. pharmaceutical regulation.<sup>129</sup>

The approval process for RU 486 is a great departure from typical FDA operation with respect to new drugs, both in its initial ban and its eventual approval.

The initial import ban on RU 486 marked a considerable political concession on the part of the FDA.<sup>130</sup>

The import ban was not based upon any expressed safety issue, and period of public comment had occurred before the administrative ban.<sup>131</sup> At the time, the FDA had a policy allowing importation of a three-month supply of unapproved drugs for personal use unless there were noted safety issues with the drug.<sup>132</sup>

A woman attempting to import a personal supply of RU 486 from the UK challenged confiscation of her supply.<sup>133</sup> The district court, when ordering that the drugs be released to the woman, stated that “the decision to ban the drug was based not [on] any bona fide concern for the safety of users of the drug, but

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<sup>129</sup>Within the abortion debate, RU 486 holds a pivotal position. Because RU 486 is administered at a stage of pregnancy much earlier than many surgical abortions are performed, it forces focus on the early stages of pregnancy, not typically the spotlight sought by the antiabortion movement. Furthermore, RU 486 has the potential to move abortion out of the abortion clinic. Such dispersal hinders typical antiabortion tactics of intimidation and confrontation of women seeking abortions.

<sup>130</sup>See Noah at 577.

<sup>131</sup>See Elizabeth A. Silverberg, Looking beyond Judicial Deference to Agency Discretion: A Fundamental Right of Access to RU 486? 59 Brooklyn L. Rev. 1551, 1563-1565, 1584-1585 (1994).

Even if the import ban on RU 486 was an interpretative rule not subject to notice and comment procedures, a court nevertheless could properly invalidate it as arbitrary and capricious. Since there was no administrative record on which to base a decision to ban the import of RU 486, the FDA's action was ill considered. Moreover, the FDA treated RU 486 differently under the personal use policy depending on how the drug was to be used. . . . Also, the agency allowed the importation of a number of unapproved drugs that posed a known health risk to users.

<sup>132</sup>See *id.* at 1572. (Citing Food and Drug Administration Regulatory Procedures Manual, Pub. No. 90-02, pt 9-71 (Dec. 11, 1989):

There has always been a market in the United States for some foreign made products that are not available domestically. . . . Individuals seek medical treatments that are not available in this country. . . . With increasing international travel and world trade, we can anticipate that more people will purchase products abroad that may not be approved, may be health frauds, or may be otherwise not legal for sale in the United States. . . . Because some countries do not regulate or restrict the commercial exportation of unapproved products, people who mail order from these businesses may not be afforded the protection of either foreign or U.S. Laws. In view of the potential scale of such commercial operations, FDA has focused its enforcement resources more on products that are shipped commercially. . . . When personal shipments of drugs and devices that appear violative are brought to FDA's attention by Customs, FDA personnel will have to use their discretion to decide on a case-by-case basis whether to sample or detain. Generally, drugs . . . subject to Import alerts are not amenable to this guidance . . . In deciding whether to exercise discretion to allow personal shipments of drug . . . FDA should consider a more permissive policy . . . when the intended use is appropriately identified, such use is not for treatment of a serious condition. And the product is not known to represent a significant health risk. . . .

<sup>133</sup>See Noah, at 578.



on political considerations having no place in FDA decisions on health and safety.”<sup>134</sup> Furthermore, the court commented that no administrative record was submitted to the court regarding the import ban, and doubted the existence of such a record, which made the FDA’s ban improper and supported a finding that the FDA ban was arbitrary or politically motivated.<sup>135</sup>

When President Clinton took office, the tide immediately changed. Clinton ordered a review of the import ban, commenting that “RU 486 has been held hostage to politics.”<sup>136</sup> The Clinton Administration then placed pressure directly on manufacturers Hoechst and Roussel-Uclaf to apply for FDA approval, a rare direct political action towards a specific pharmaceutical product.<sup>137</sup> Once finally under review, *mifepristone*, the main abortifacient component of the RU 486 cocktail, underwent an specialized review process for accelerated approval, a process typically reserved for life saving drugs like those developed to treat AIDS. Such review allows the FDA to place greater restrictions on a drug post-approval than those drugs approved through the regular process.<sup>138</sup> Indeed, the FDA did suggest distributional restrictions similar to those of Schedule II controlled substances, although most restrictions were removed upon final approval of RU 486 in 2000.<sup>139</sup> The approval did require labeling that called for physicians to administer the entire drug cocktail over the course of two patient visits rather than dispensing the pills for home use, followed by a final third visit to check on the success of the RU 486 regimen.<sup>140</sup> In another departure from normal procedures, off-label use of

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<sup>134</sup>See *id.* (Citing *Benten v. Kessler*, 799 F. Supp. 281, 286(E.D.N.Y. 1992). (granting a preliminary injunction due to the petitioner’s likelihood of success on the merits of her claim that this limitation should have undergone notice-and-comment rulemaking procedures.) See generally, Silverberg at 1575-1586. (“In concluding, the district court indicated that while the court did not need to reach the question whether or not the import ban was arbitrary and capricious, [the petitioner] had demonstrated a substantial likelihood that the import ban could be struck down on those grounds as well.”)

<sup>135</sup>See *id.* at 1588, 1590. (“The absence of any relevant documents in FDA files relating to deliberations about safety, possible importations or examples of RU 486’s use in this country implies a single, undisputed conclusion: the FDA did not issue the automatic detention order for RU 486 based on any substantive research or independent investigations.”)

<sup>136</sup>See Noah at 578.

<sup>137</sup>See *id.*

<sup>138</sup>See *id.* at 580-581.

<sup>139</sup>See *id.* at 584-585.

<sup>140</sup>See *id.*

RU 486 is expressly condemned by the FDA.<sup>141</sup> It also must be remembered that the RU 486 regimen involves the administration of another drug in addition to *mifepristone*, a *misoprostol* to cause uterine contractions. In an additional unusual action by the FDA pressured Searle to cross label its *misoprostol* drug Cytotec for use with *mifepristone*.<sup>142</sup>

## 2. Legal distinctions between contraceptives and abortion

The flexibility of the FDA to pressures of the abortion debate becomes particularly problematic in light of the current contraceptive technology and its legal implications. The approval of RU 486 and post-coital contraceptives blurs the boundary between contraception and abortion in the legal context. Such blurring may revert contraception and abortion to their intertwined legal status of the 1960s and 1970s. After *Griswold* and *Eisenstadt*<sup>143</sup>, which secured the right to access to birth control the court slowly distinguished between the legal status of birth control and the legal status of abortion. The Court in *Carey v. Population Services International* secured a constitutional right to access to birth control but maintained an interconnection with abortion, stating that restrictions on either must survive strict scrutiny.<sup>144</sup>

*Planned Parenthood v. Casey* then represented a solid divergence between abortion and birth control legal

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<sup>141</sup>See *id.* at 586. Thus, the contraceptive application of mifepristone is not available in the U.S.

<sup>142</sup>See *id.* at 589-90. Searle was reluctant to participate in the RU 486 controversy and actually advised its prescribing physicians against abortifacient use of Cytotec. Cross labeling is typically prohibited by the FDA unless both drugs have been approved for their use together.

<sup>143</sup>See *Eisenstadt* at 453. (“If the right to privacy means anything, it is the right of the individual, married or single, to be free from unwarranted governmental intrusion into matters so fundamentally affecting a person as the decision whether to bear or beget a child.”)

<sup>144</sup>See *Noah* at 1604-1605. (stating that the Court in *Carey* concluded “that the right to birth control is fundamental, and that any state regulation involving contraceptives must be based on compelling state interest and must be narrowly tailored to meet the asserted interest. . . . *Carey* expresses this underlying principle [as linked to abortion] by noting that the right to contraceptives should be seen not as constitutionally distinct but as part of the ‘constitutionally protected right of decision in matters of childbearing that is the underlying foundation of the holdings in *Griswold*, *Eisenstadt v. Baird*, and *Roe v. Wade*.”) See also *Carey v. Population Services International*, 431 U.S. 678, 688-9 (1977). (Stating that “the significance of these cases is that they establish the same test must be applied to state regulations that burden an individual’s right to decide to prevent conception or terminate pregnancy by substantially limiting access to the means of effectuating that decisions as is applied to state statutes that prohibit the decision entirely . . . This is so not because there is an independent fundamental “right of access to contraceptives,” but because such access is essential to exercise the constitutionally protected right of decision in matters of childbearing that is the underlying foundation of the holdings in *Griswold*, *Eisenstadt v. Baird*, and *Roe v. Wade*.” Emphasis added.)

theories.<sup>145</sup> The Court in Casey strongly supported a fundamental right to birth control while allowing more restriction on abortion at the state level and removing the strict scrutiny previously required of abortion regulation.<sup>146</sup> Casey, however, was decided prior to the FDA approval of emergency contraceptives or RU 486. It is now unclear if such legal distinctions can feasibly be maintained. While post-coital contraceptives are apparently grouped in the contraceptives pharmaceutical category, they target the post-conception phase of reproduction and thus could alternatively be considered abortifacients. A changed political climate that focuses on conception would easily shift emergency contraceptives into the more easily restricted abortion category. RU 486 is clearly treated as an abortifacient, although it does have contraceptive capability. Furthermore, traditional contraceptives, post-coital contraceptives, and RU 486 all utilize technology derived from the same chemical family (derivatives of estrogen and progesterone) and thus chemically, if not legally, are hard to distinguish. Therefore, as the law catches up with science, it is possible if not likely that the distinctions drawn in Casey will dissipate. In that case, there is little legal authority to check the political forces visited upon access to contraceptives, thereby creating considerable uncertainty as to the future status of the contraceptives market. Collapsing contraception into the abortion debate will only serve to further discourage contraceptives research and development. To prevent further exodus from contraceptives R&D that will occur as contraception is pulled into the abortion maelstrom, policy, either on part of the FDA or a legal entity will have to distinguish contraception and abortion in a manner that consistent with the technological correlations between them. A viable distinction may require relinquishing post-coital contraceptives and RU 486 fully to the abortion camp, but this would be worthwhile if such action succeeded in assuring greater security for contraception overall.

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<sup>145</sup>505 U.S. 833 (1992).

<sup>146</sup>See Noah at 1606.

### III. Suggestions for removing the roadblocks to development

The problems contributing to a lack of research and development in the field of contraceptives do not have a simple solution. Rather, any improvement of the situation will involve changes in political alliances, laws, funding, and traditions of research. In order to ensure more consistent political support, contraceptives research must find a way to separate itself from the abortion debate – a seemingly insurmountable task. In light of recent advances in post-coital contraceptives and abortifacients utilizing the same technology as traditional contraceptives, the feasibility such separation is unlikely. Therefore, regardless of any other legal, economic, or political strategy, contraception will always have strong, politically organized opponents. The FDA, as a government agency, regardless of its claims of independence, will not be able to wholly avoid political pressures to follow the prevalent sentiments towards contraceptives of any particular moment in time. Such pressure played an obvious role in the heightened clinical requirements in place from 1969 to 1989 and in the rocky treatment of RU 486. In order to overcome potential opposition to research, steps need to be taken to smooth the R&D process and incentivize pharmaceutical manufacturers to produce existing and new forms of contraceptives.

First and foremost, the threat of overwhelming product liability must be dampened by insulating manufacturers from suit under a regime that accepts the FDA defense. As discussed, *supra*, the tremendous costs associated with meeting the FDA standards for safety and efficacy already chill R&D, and the threat of products liability provides an additional layer of the chilling effect. Since side effects are virtually unavoidable, compliance with the FDA testing requirements should eliminate any product liability based on the technology itself, and not the quality of its manufacture. Injuries from approved drugs can be covered under

existing healthcare structures. Furthermore, health care structures will serve as an additional level of production for consumers. If a drug has been approved by the FDA but somehow continues to have frequent and costly side effects (even if not sufficient for the FDA to step in), health care providers can choose not to prescribe the drug or, if the drug is available over-the-counter, can advocate the drug's removal from the market. Legal relief will still be available when FDA and health care provider protections fail, namely in cases of product defect or fraud, but manufacturers will not face the constant threat of lawsuits for products that are inevitably risky. In addition, as a pre-condition to FDA approval, the FDA could mandate that a certain percentage of the proceeds from the sale of contraceptives be put into a fund to supplement insurance compensation of those injured by side effects of contraception. With such a system, those who suffer the side effects of contraceptives would be compensated, and all consumers of contraceptives would share the risk of injury by paying a small premium on the price of the drugs. While this paper notes that the cost of contraception is already prohibitive for many people, over time, without the costs of litigation built into the price of contraceptives, the price would drop even if a premium for the fund is attached.

While a necessary step, an FDA defense will not work by itself to increase contraceptives research and development. Liability protection for vaccinations, which have a much wider market than contraceptives, was not a sufficient impetus for significant new R&D. Liability protection alone will certainly not create the incentives needed for more research and development of contraception. To remedy the problem, all health insurers and prescription plans should be required to cover contraception in every form approved by the FDA unless they bring an effective challenge to approval based on safety reasons. In addition to creating more gender equity in health care, coverage will expand the market for technologically advanced contraception, thus providing greater incentives to develop new methods of contraception. As long as coverage is limited to a minority of insurance plans and forms of contraception, demand for contraceptives will be artificially

constricted. Once insurers provide coverage, it is likely that more users of non-steroid contraceptives such as condoms, spermicides, and other barrier methods of contraception will opt to try steroid contraception. With an expanded consumer base, manufacturers will have a reason to provide a greater range of steroid contraception offerings.

Finally, public funding should increase. Two goals are often linked with increased contraceptive offerings: domestic teenage pregnancy<sup>147</sup> and population growth in underdeveloped nations. Neither provide great profit potential, and it is therefore unlikely that any new contraceptives research would be aimed as products accessible specifically to those two groups.<sup>148</sup> Both are public goals. The political link between contraception and abortion has made domestic public funding for research and development a source of uncertainty, but a global treatment of contraception may prove more consistent.<sup>149</sup> The World Health Organization should continue its active role in funding research and development of contraception.<sup>150</sup> The FDA, in turn, should grant greater deference to contraceptive drugs developed and approved abroad and not embroil them in years of political tug of war, as was the case with the RU 486.

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<sup>147</sup>See Brown at 3. (Citing Suzanne F. Delbanco et al., Missed Opportunities: Teenagers and Emergency Contraception, 152 Archives Pediatrics Adolescent Med. 727, 727 (1998)) Approximately 112 per 1000 girls ages 15 to 19 become pregnant in the U.S. each year.

<sup>148</sup>See Djerassi at 77. "When it comes to the market delivering contraceptive innovations, the critics ignore the key point that the features of a truly novel contraceptive (say a contraceptive vaccine or a once-a-month menses-inducing pill) associated with major societal advantages (e.g. low cost and long duration for a vaccine; short action and minimal pill consumption involving 13 pills/year for a menses-inducing versus 250 pills or more per annum for current oral contraceptives), are precisely what would keep companies, which search for billion-dollar drugs used daily, from re-entering the contraceptive field."

<sup>149</sup>The monthly cost of the Pill increased by a factor of ten between 1977 and 1989 alone, largely as a result of continuous litigation. Djerassi, *The Bitter Pill*, at 357. Alleviating the constant costs of litigation would help to slow the rising prices of contraception.

<sup>150</sup>See generally Diczfalusy at 185-200.

## Conclusion

Steroid contraception has had a tremendous impact on notions of family and gender in the United States. As its roots in eugenics continue as a driving, if less conspicuous, force in research and development, the actual progress of contraception has slowed. Despite the surge of technological progress that has occurred in medicine in the past half century, progress in contraception has merely trickled, largely due to the politics of abortion and their continuous, divisive impact on FDA policy. Repeated and costly product liability suits have also slowed contraceptives research and development, as has a lack of insurance coverage that limited the market for new methods of contraception. While the ties to abortion will be difficult to sever, the problems of liability costs and the limited market could be alleviated through an FDA defense to product liability and mandated full insurance coverage for steroid contraception. An FDA defense would recognize the inherent risk of contraceptives and alleviate liability burdens for manufacturers in compliance with FDA standards while at the same time compensating those who suffer the adverse effects of contraceptives. Expanding healthcare coverage to contraception would remove artificial constraints on the contraceptives market. At the same time, requiring insurers to cover contraception would force them to monitor adverse effects, and encourage them to petition to the FDA for removal of approval of drugs whose effects were too frequent or costly. Therefore contraceptive consumers would have an added layer of protection from contraception where risk outweighed benefit without appealing to the torts system. In addition to these reforms, contraceptives research requires consistent and significant public funding in order to better serve those sectors that are not profitable for private contraceptives research, but in dire need of improved contraceptives access.

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